#28 2.605

Serial No. 09/160,618

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re U.S. Patent Application)
)
Applicant: Edwin Christensen)
)
Serial No.: 09/160,618)
)
Filed: September 24, 1998)
)
For: **SEMI-MOIST ORAL DELIVERY SYSTEM**)
)
)

DECLARATION OF EDWIN CHRISTENSEN UNDER 37 CFR §1.132

Commissioner for Patents
Washington, D.C. 20231

I, Edwin Christensen, hereby declare as follows:

1. I am the sole inventor of the invention described and claimed in the above-identified patent application.

2. I, therefore, am familiar with the subject matter described in the above-identified application, and with the chemistry and chemical functions involved therewith.

3. Based on my knowledge and experience with such chemistry, it is my belief that the existence of sucrose in the product of the subject invention is critical to the operation of the invention.

4. If one uses a sweetener other than sucrose, such as fructose, xylose, dextrose or maltose, then the physical properties of the resulting product are changed substantially primarily because of the different crystallizing action taken by these sweeteners.

5. Such non-sucrose sweeteners do not crystallize sufficiently at the temperatures involved and thus do not sufficiently bind the product to retain a shape or

result in a product with excessive hardness or crystallize excessively so as to become too hard.

6. In the case of fructose, this sweetener is so hygroscopic as to "puddle" when used in the amounts necessary in the subject invention, that is create a pool of water when exposed to the atmosphere. As such, integrity of product and hygienic consideration dominate and mandate that it cannot be used.

7. As an example of the above-described phenomenons, I conducted experiments incorporating the ingredients of the subject invention as well as substituting different sweeteners for sucrose.

8. In each experiment the ingredients were mixed and extruded as set forth in the subject application. The extruded products were cut into discrete pieces.

9. The following experiments were performed:

	Sucrose Type	Sucrose %	Starch %	Corn Syrup %	Sorbitol %	Water %	Result
1.	Sucrose	26.6	19.2	15.1	18.8	20.3	Soft, pliable, flexible, that holds its shape with a very sweet, non-gritty taste.
2.	~~Fructose~~ Dextrose	"	"	"	"	"	Tough, chewy, moderate sweetness, and a wet slippery feel-gets hard
3.	~~Dextrose~~ Maltose	"	"	"	"	"	Rubbery, very chewy, non-sweet-eventually gets hard as rock
4.	~~Maltose~~ Fructose	"	"	"	"	"	Slimy, very sticky, wet looking, very sweet hygroscopic
5.	Lactose	"	"	"	"	"	Tough, rubbery, sandy tasting, non-sweet-hard

10. When sweeteners other than sucrose were used, excessive amounts of binder were necessary to supply the binding power found by the crystallization powers

of sucrose; and yet remain soft and pliable in texture.

11. Therefore I have concluded that sucrose, of the above sweeteners, is the only sweetener, which is operative in the formulation of the subject invention and achieves a lasting chewy, non-gritty texture with a sweet taste.

The following base matrix was utilized to show the effects of substituting different "sugars" for sucrose. These tests were conducted without an active ingredient. To achieve high levels of active the sugar level is reduced while maintaining the starch level. Increasing levels of active ingredients; as is required, the sucrose level is reduced while maintaining the starch level. Increasing levels of the active ingredient also require the sucrose to provide strength to the matrix well maintaining texture, mouth feel, sweetness, pliability, non-slime appearance, in addition to moisture control.

12. All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further, these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code, and that such willful, false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

Date: 2-29-02

Edwin Christensen

Edwin Christensen

FACSIMILE COVER LETTER

FROM: Gerald T. Shekleton, Esq. DATE: February 1, 2002

WELSH & KATZ, LTD.
120 South Riverside Plaza
22nd Floor
Chicago, Illinois 60606

Facsimile Number - (312) 655-1501
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Number of pages, including this cover letter 4

TO: Todd Ware

FIRM/COMPANY: U.S. Patent and Trademark Office

Facsimile Number: (703) 746-3161

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******** CONFIDENTIALITY NOTE ********

COMMENTS:

6506-73690

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re U.S. Patent Application	
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Serial No.:	09/160,618
Filed:	September 24, 1998
For:	**SEMI-MOIST ORAL DELIVERY SYSTEM**
Examiner:	T. Ware

SUPPLEMENTAL AMENDMENT

Box NON-FEE AMENDMENT
Commissioner for Patents
Washington, D.C. 20231

Sir:

IN THE CLAIMS:

Please amend claims 1, 12, and 26 as follows:

1. (four times amended) A composition for the oral administration of an additive selected from the group consisting of pharmaceutical, nutritional supplements, vitamins and minerals, and mixtures thereof to mammals in a discrete dosage form, said discrete dosage form comprising:

said additive,

an extrudate comprising a matrix having

about 10 to about 50% wt starch,

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a sweetener consisting essentially of sucrose, corn syrup and sorbitol,said sucrose being in an amount of at least 10%, and

at least about 5% wt water

said composition having an A_w of about 0.60 to about 0.75, and a soft and chewy texture, and said A_w being adjusted to permit an appropriate amount of free water in the presence of the additive.

9 ~~12.~~ (thrice amended) A method of making a carrier and additive mixture for use in an oral administration of a therapeutically effective amount of the additive in discrete dosage form, comprising the steps of:

a) forming a matrix and additive admixture by mixing, in a one-step procedure

additive,

about 10 to about 50% wt starch,

0 to about 40% wt fat or oil,

a sweetener consisting of sucrose, corn syrup and sorbitol, said sucrose being in an amount of at least 10%,

and water,

and mixing;

adjusting the relative amounts of polyhydric alcohol and water to control the A_w of said admixture to adjust the level of moisture in the carrier to be a level not inimical to the additive and extruding said admixture to form an extrudate.

23 ~~26.~~ (twice amended) A composition for the oral administration of a pharmaceutical additive to mammals in a discrete dosage form, said discrete dosage form comprising:

an extrudate having a matrix, and comprising:

10-50% starch,

0-40% fat or oil,

a sweetener consisting essentially of sucrose, corn syrup and sorbitol, said sucrose being in an amount of least 10%,

at least about 5% water,

said composition having an A_w of about 0.60 to about 0.75, and a soft and chewy texture, and said A_w being adjusted to permit an appropriate amount of free water in the presence of the additive,

REMARKS

By the amendments, Applicant has incorporated the Examiner's suggestions as to the form of the claim as and as amended, believe they conform to that discussed in the interview held January 29, 2001.

Further, Applicant hereby encloses a copy of the revised Declaration submitted at the above noted interview. As stated therein, this revised Declaration corrects several typographical errors found after submission of the original Declaration.

Applicant hereby requests reconsideration and reexamination thereof.

With the above amendments and remarks this application is considered ready for allowances and applicant earnestly solicits an early notice of same. Should the Examiner be of the opinion that a telephone conference would expedite prosecution of the subject application, he is respectfully requested to call the undersigned at the below listed number.

Date: February 1, 2002

Respectfully submitted,

WELSH & KATZ, LTD.

By Gerald T. Shekleton
Gerald T. Shekleton
Registration No. 27,466

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Chicago, Illinois 60606-3913
Telephone: 312/655-1500

MARKED UP VERSION TO SHOW CHANGES MADE

1. (four times amended) A [carrier] composition for the oral administration of an additive selected from the group consisting of pharmaceutical, nutritional supplements, vitamins and minerals, and mixtures thereof to mammals in a discrete dosage form, said [carrier comprising] discrete dosage form comprising:

said additive,

an extrudate [including] comprising a matrix having

about 10 to about 50% wt starch,

a sweetener consisting essentially of sucrose, corn syrup and sorbitol, said sucrose being in an amount of at least 10%, and

at least about 5% wt water

said [carrier] composition having an A_w of about 0.60 to about 0.75, and a soft and chewy texture, and said A_w being adjusted to permit an appropriate amount of free water in the presence of the additive.

12. (thrice amended) A method of making a carrier and additive mixture for use in an oral administration of a therapeutically effective amount of the additive in discrete dosage form, comprising the steps of:

a) forming a matrix and additive admixture by mixing, in a one-step procedure

additive,

about 10 to about 50% wt starch,

0 to about 40% wt fat or oil,

a sweetener consisting of sucrose, corn syrup and sorbitol, said sucrose being in an amount of at least 10%,

and water,

and mixing;

adjusting the relative amounts of polyhydric alcohol and water to control the A_w of said [carrier] admixture to adjust the level of moisture in the carrier to be a level not inimical to the additive and extruding said [carrier and additive] admixture to form an extrudate.

26. (twice amended) A composition [carrier] for the oral administration of a pharmaceutical additive to mammals in a discrete dosage form, said [carrier] discrete dosage form comprising:

an extrudate having a matrix, and [including] comprising:

10-50% starch,

0-40% fat or oil,

a sweetener consisting essentially of sucrose, corn syrup and sorbitol, said sucrose being in an amount of least 10%,

at least about 5% water,

said [carrier] composition having an A_w of about 0.60 to about 0.75, and a soft and chewy texture, and said A_w being adjusted to permit an appropriate amount of free water in the presence of the additive.

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